REMARKS

Claims 1-55 are pending in this application. Claims 1-19 remain in this application. Claims 1-4, 14 and 15 are amended. Claims 20-55 were previously withdrawn from consideration. The Examiner is respectfully requested to enter the amendments set forth above and the following remarks into the record.

I. Rejection of Claims Under 35 U.S.C. 112

Claims 2-4 and 14-15 stand rejected as failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims were rejected because the Examiner found that the connector filter and the outlet filters as recited in the claims were unclear as to how they structurally cooperated with the other structures in the culture system.

Claims 2-4 and 14-15 have been amended to clarify the structural cooperativity of the connector and outlet filters with the other structural components of the culture system.

II. Rejection of Claims Under 35 U.S.C. 103(a)

The Examiner rejected claims 1-19 under 35 U.S.C. 103(a).

Independent Claim 1 and Dependent Claims 2-13

Claim 1-4 and 6-13 were rejected under 35 USC 103(a) as being unpatentable over Marx et al.(US 6,255,106) in view of Ghezzi et al. (US 5,194,157).

Applicant traverses the rejection for the reasons discussed below.

A. Marx et al. (US 6,255,106)

Marx et al. discloses a culture system having culture modules having multiple cell populated spaces within a module wherein these cell populated spaces are in a common fluid supply circuitry. The Examiner has interpreted two of the cell populated spaces within a module as similar to the first fluid culture compartment and the second fluid culture compartment of the present invention. However, each cell populated space is surrounded by a filter membrane 14, not a fluid-impenetrable

housing. Claim 1(b) of amended claim 1 calls for a first fluid culture compartment having a fluid-impenetrable housing. Module 7 or 9 of Marx et al. is similar to this culture compartment, not the cell populated spaces 12.

The modules 7 or 9 of Marx et al. are not "coaxially" aligned as recited in claim 1(d). The coaxial alignment of the first and second culture compartments of the present invention directs the media from the first culture compartment into the second culture compartment and on out of the system.

Secondly, Marx et al. do not describe a fluid connector having a through bore interconnecting two axially aligned culture chambers, where the fluid connector has a first side mounted on a second end of the tubular housing (on the opposed end from the fluid inlet) of the first culture chamber and a second side mounted on the proximal end of the second culture compartment.

Thirdly, Marx et al. do not describe a connector filter mounted on the first side of the fluid connector that filters "a fluid stream passing out of the first culture compartment and into the through bore of the fluid connector."

Fourthly, Marx et al. do not describe "an outlet filter" having one end mounted on a proximal side of the distal end piece mounted on the distal end of the second culture compartment.

Although, Marx et al. do show the interconnection of two modules (see Figure 2), the arrangement and function of the interconnected modules is different from the present invention and the interior filters 14 surrounding the cell populated spaces are different from the connector filter and the outlet filter. For example, at column 2, lines 31-33, the interconnecting modules are described as "connected to cell-populated culture spaces of other modules via a microfiltration membrane (11), independently of the supply cycle." In contrast, the culture chambers of the present invention are not independent of the supply cycle. The fluid passes from the first culture chamber through the connector filter into the through bore of the fluid connector, into the second culture compartment, and out the fluid outlet.

B. Ghezzi et al. (US 5,194,157)

Ghezzi et al. discloses an interlinked haemofiltration element and a haemodialysis element not an interlinked cell culture system. The blood purification system described by Ghezzi et al.

passes whole blood from the patient, through an inlet connector 4, the haemofiltration element 2, the duct 6, the haemodialysis element 3, the outlet connector 5, and back into the patient (see column 2, lines 61-68).

Ghezzi et al. do not describe a connector filter mounted on the first side of the fluid connector that filters "a fluid stream passing out of the first culture compartment and into the through bore of the fluid connector."

Furthermore, Ghezzi et al. do not describe "an outlet filter" having one end mounted on a proximal side of the distal end piece that mounted on the distal end of the second culture compartment.

C. Combination of Marx et al. and Ghezzi, et al.

To establish a prima facie case of obviousness, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Furthermore, the prior art must teach or suggest all claim limitations.

First of all there is no suggestion or motivation to combine the coaxial alignment and fluid connector of the haemofiltration element and a haemodialysis element of Ghezzi, et al. with the cell culture modules of Marx, et al. The blood purification system of Ghezzi, et al. has two units (a haemofiltration element and a haemodialysis element) operating on whole blood passing through from one element to the other. In contrast, the culture compartments of the present invention, like the culture modules of Marx, et al. do not circulate the cells from a first compartment or module to a second compartment or module. Rather the cell culture systems circulate media into and out of the compartments or modules and retain the cells within the compartments or modules using filters.

Furthermore, blood purification using a haemofiltration element and a haemodialysis element is typically done in a clinical setting and is done by persons trained to deal with clinical problems. In contrast, the culturing of cells in cell culture systems is typically performed by researchers growing cells and is not typically related to patient activity and the clinic. The skills and concerns of persons trained to work with a haemofiltration element and a haemodialysis element is quite different from the skills and concerns of persons trained to grow cell cultures and to produce the cell products such

as monoclonal antibodies. Thus, the references do not suggest a combination of the design of the blood purification equipment with the cell culture system. It is inappropriate to use the claim as an outline for citing one component from one reference and another component from another reference without any suggestion or hint as to how or why one would or even could combine the reference teachings.

In addition, neither the Marx patent nor the Ghezzi patent describe a connector filter and an outlet filter as set forth in claim1. Marx, et al. do not describe a connector filter having one end mounted on the interior side of a fluid connector, nor does Marx, et al. describe an outlet filter having one end mounted on a proximal side of the distal end piece of a second culture compartment. Likewise, the blood purification device described by Ghezzi, et al. does not have a structural element similar to the connector filter or the outlet filter. The haemofiltration element uses an exterior filter to filter the blood that passes through haemofiltration element. The filtrate is processed and added back into the whole blood as it passes through the duct 6, the whole blood then goes through the haemodialysis element. The system is designed to circulate blood from the patient and back into the patient and does not include a connector filter mounted on the interior side of the duct to filter the blood passing from the haemofiltration element into the duct. Nor does the blood purification device have an outlet filter. Since neither patent teaches a connector or outlet filter, then the combination of the two patents does not teach a connector or outlet filter.

D. Dependent Claims

Claims 2-13 depend on claim 1 or one of its other dependent claims. Since each of these dependent claims contain all of the limitations of their respective independent claims, the Examiner's rejection of claims 2-13 is obviated for the reasons set forth above.

Independent Claims 14 and 19 and Dependent Claims 5, 15-18

Claims 5 and 14-19 were rejected as being unpatentable over Marx et al. (US 6,255,106) in view of Ghezzi et al. (US 5,194,157) taken further in view of Schwarz et al. (US 5,025,650) or Akers et al. (US 2004/0110273).

Applicants traverse the rejection for the reasons discussed below.

A. Marx et al. and Ghezzi, et al.

Marx, et al. and Ghezzi, et al. differ from the Applicants invention set forth in independent claims 14 and 19 for similar reasons as discussed above for independent claim 1.

B. Schwarz, et al.

The Examiner found that the reference of Schwartz et al. discloses that it is known in the art to provide a membrane bioreactor using a single tubular membrane provided on a membrane support (Figs. 1-3).

The bioreactor of Schwartz, et al. has a central support member (32) with an oxygen permeable membrane (40) disposed over the central support member. See column 5, lines 36-38. In contrast, the present invention has a molecular weight cut-off membrane as opposed to an oxygen permeable membrane. The membrane 40 described by Schwartz, et al. "operates under air pressure to permit oxygen to permeate through the wall of the membrane and carbon dioxide to diffuse in the opposite direction." See column 5, lines 43-53. The invention of Schwartz, et al. would not work if liquid or media could penetrate the membrane. If media could penetrate membrane 40 the media would diffuse out of the annulus of fluid medium surrounding the membrane without being replenished. Thus, Schwartz, et al. actually teach away from the use of a molecular weight cut-off membrane.

Furthermore, the air passageway through "the annular space between the inner wall of the membrane 40 and the outer wall of the central support member 32" is not in fluid communication with the through bore of the fluid connector as claimed in claim 14 (e), and 19 (i).

In addition, there is no suggestion or motivation to combine the central support member (32) and the oxygen permeable membrane (40) with the haemofiltration element and a haemodialysis element of Ghezzi, et al. or with the cell culture modules of Marx, et al.

C. Akers, et al. is Commonly Owned and is Not Prior Art under 35 U.S.C. 103(c)

Publication No. US 2004/0110273 A1 of Akers, et al. should not be considered prior art for the present invention because Application No. 10/821,455 and Publication No. US 2004/0110273 A1 of patent application 10/725,607 were, at the time the invention of

Application No. 10/821,455 was made, subject to an obligation of assignment to Synthecon, Inc.

D. Dependent Claims

Claim 5 depends on claim 1 and claims 15-18 depend on claim 14 or one of its other dependent claims. Since each of these dependent claims contain all of the limitations of their respective independent claims, the Examiner's rejection of claims 5 and 15-18 is obviated for the reasons set forth above.

III. Conclusion

In view of the foregoing amendments and remarks, it is respectfully submitted that Applicant has responded in a fully satisfactory manner to all matters at issue in this Office Action. If the Examiner has any questions or suggestions concerning the application, or feels that an interview would advance the examination process, the Examiner is requested to call the Applicant's undersigned attorney at the direct dial number printed below.

Respectfully submitted,

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DATE: June 22, 2005

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